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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/345,148	06/30/1999	ANDREW H. SEGAL	3378/80490	9870
29933	7590	04/12/2006	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/345,148	SEGAL, ANDREW H.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-16,19-68,70 and 71 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,19,20,27 and 30-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-14,21-26,28,29,70 and 71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment, filed 12/27/05, has been entered.

Claim 17 has been canceled. Claims 2, 18 and 69 have been canceled previously

Claims 1, 3, 5, 6, 11, 21, 23, 26, 28, 29 and 70 have been amended.

Claim 71 has been added.

Claims 1, 3-16, 19-68 and 70-71 are pending.

Claims 15-16, 19, 20, 27 and 30-68 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions and/or species.

Claims 1, 3-14, 21-26, 28, 29 and 70-71 are being acted upon as the elected invention.

For the record, applicant's election of the species CD40-specific antibody, alpha chain of C3b and IL-2 in Paper No. 10, filed 4/5/01 and in Paper No. 13, filed 12/19/01, has been acknowledged.

However, the issues of whether claim 25, drawn to pathogenic cells selected from the group consisting of a bacterium, a virus, a fungus a cell of parasite should have been withdrawn from the elected invention, given that the rejection of record appears to be drawn to tumor cells as the elected species for pathogenic cells"

Applicant is invited to clarify the elected species of pathogenic cells.

If applicant has not elected a species of pathogenic cells, the following is set forth.

2. This application contains claims directed to the following patentably distinct species of the claimed elected invention wherein the cell is:

- A) a bacterium,
- B) a virus,
- C) a fungus,
- D) a cell of parasite,
- E) a tumor cell,
- F) a nucleated cell or
- G) a procaryotic cell.

These species are distinct because the read on vaccinating mammals to antigens associated with pathologies that differ in etiologies and therapeutic endpoints. Therefore, they are separate and patentably distinct species.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, currently, claim 1 is generic.

Although it appears that this application has been prosecuted with an election of "tumor cells", such an election is not readily apparent and whether claim 25 is part of the elected invention / species remains ambiguous.

3. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Upon a review of the prosecution history of the instant application, including applicant's most recent amendment, filed 12/27/05,

the examiner is requesting clarification of the metes and bounds of the instant claims, including how the metes and bounds read on the elected invention.

Applicant continues to assert that the prior art does not teach a composition comprising an antigen bearing cell and an exogenous engineered ligand for CD40.

It is still unclear as to *whether the "exogenous ligand for CD40 (e.g. anti-CD40 antibodies or CD40 ligand)" is expressed by the "antigen bearing cell or not".*

Previously, the claims recited an "admixture" and now the claims recited "and".

Applicant is invited to clarify whether the cell comprising an antigen" and the engineered ligand for CD40 are *separate elements or not* in the claimed compositions employed in the claimed methods.

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For example, it is not clear

(a) whether all or some of the elements of the claims, namely "the cell", "the engineered ligand for CD40" and "the cytokine" all comprise "a lipid" and in turn, "a GPI moiety, a fatty acid, or palmitate" as separate elements to each of "the cell", "the engineered ligand for CD40" and "the cytokine" or

(b) whether "comprising the lipid, GPI moiety, fatty acid or palmitate" reads on either "the cell comprising an antigen" itself (e.g., given the "comprising" language) or

(c) "the cell comprising the antigen and the engineered ligand" all-together is meant to read or these claim "limitations".

As both applicant and the examiner have addressed previously, the interpretation of these claims have been confusing.

The examiner is considering re-opening on the broadest reasonable interpretation of these claims as reading simply on two separate elements to the composition employed in the claimed methods.

One element would read on a "cell comprising an antigen" with dependent claims reading on an "opsonin-enhanced cell" comprising "alpha chain of C3b" as the elected species and a separate element which comprises simply a ligand for CD40 (e.g. anti-CD40 antibodies or CD40 ligand) comprises "any moiety" and in certain dependent limitations, comprising "a lipid, a GPI moiety, fatty acid or palmitate".

Further, it appears that the "cytokine" can be a separate element of the composition or an element of the "cell comprising an antigen".

The examiner apologizes for any inconvenience to applicant in this matter.

However, rather than having the examiner and the applicant continue to interpret the claims differently and the length of this particular issue in the instant application,

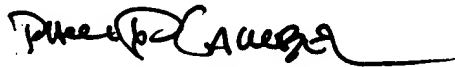
the examiner is making this request to clarify the interpretation of claims in the interest of furthering compact prosecution and avoiding an unnecessary final rejection.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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April 4, 2006